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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,419	04/20/2004	Alfred Berchielli	PC25684A	5347

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
GROTON, CT 06340

EXAMINER	
AHMED, HASAN SYED	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
04/21/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	10/828,419	BERCHIELLI ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,8-12 and 31-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 8-12, and 31-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants' (1) terminal disclaimers, filed on 15 January 2008; and (2) amendment and RCE, filed on 7 February 2008.
- The 35 USC 112 rejection is withdrawn in view of the amendment.

* * * * *

Terminal Disclaimer

The terminal disclaimers filed on 15 January 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on U.S. Application No. 10/828,079 and 10/828,398 have been reviewed and is accepted. The terminal disclaimers have been recorded.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 8-12, and 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson, et al. (WO 99/36060) in view of Kerc, et al. (WO 02/072073).

Wilson, et al. disclose an oral dosage form (*see* page 1, lines 10-19). The dosage form is comprised of:

- the atorvastatin prepared without a granulation step of instant claim 1 (*see* page 5, line 28; examples 1-39);
- the less than about 5% alkalizing agent additive of instant claims 1, 31, (*see* page 10, lines 18-22; examples 1-39);
- the excipient of instant claim 3 (*see* page 7, lines 7-24);
- the less than about 5% alkaline earth metal salt additive of instant claim 6 (*see* examples 1-39);
- the less than about 5% polymeric amide or polymeric amine additive of instant claims 7 and 32 (*see* examples 1-39);
- the at least one active drug in addition to the atorvastatin of instant claim 17 (see page 3, line 23); and
- the inorganic and organic bases of instant claims 34 and 37

The use of a capsule filler or tablet press recited in instant claim 2 is not essential to a determination of patentability of the composition disclosed in the claim. As explained by the court in *In re Thorpe et. al.* (CAFC 1985) 779 F2d 695, "A claim to a composition defined by reference to the process by which it is produced, is not limited to compositions produced by the process recited in the claim."

The Wilson, et al. reference is silent with respect to potency, as recited in instant claim 1. Applicants' composition contains the same components in the same configuration as the prior art. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the

claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

Wilson, et al. explain that their dosage form is beneficial because it results in an enhanced rate and degree of absorption of a pharmaceutically active agent, while minimizing gastric irritation (*see* page 1, lines 10-14).

Wilson, et al. do not explicitly disclose the somewhat disordered (amorphous) forms of atorvastatin recited in instant claim 4, however these forms were known in the pharmaceutical art at the time the instant application was filed (*see* Kerc, et al., abstract; page 5, lines 12-16; tables 1 and 4; page 10, lines 8-13; and examples 1-6).

While Wilson, et al. do not explicitly teach the segregation numbers of instant claims 12 and 15, the mean particle diameter of instant claim 14, the alkalinizing agent concentration of instant claims 33 and 36, the amide or amine concentration of instant claims 35 and 38, or the diluent concentration of instant claim 1, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable segregation, particle diameter, and diluent concentration by routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in segregation, particle diameter, or concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454,

456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant segregation number, particle diameter, or diluent concentration.

Wilson, et al. do not explicitly teach the diluents of instant claim 1 (e.g. microcrystalline cellulose). Rather, they teach use of the diluents hydroxypropylmethylcellulose and hydroxypropylcellulose (*see* page 7, lines 14-16). Because microcrystalline cellulose, hydroxypropylmethylcellulose and hydroxypropylcellulose are all carbohydrate-based dispersing agents, one of ordinary skill in the art would have been motivated to add microcrystalline cellulose, hydroxypropylmethylcellulose or hydroxypropylcellulose to the instant composition. There is a reasonable expectation that the addition of microcrystalline cellulose, hydroxypropylmethylcellulose or hydroxypropylcellulose to the instant composition would provide an effective diluent. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add either microcrystalline cellulose, hydroxypropylmethylcellulose or hydroxypropylcellulose to the instant composition.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a unit dosage form comprising a somewhat disordered form of atorvastatin without a granulation step, as taught by Wilson, et al. in view of Kerc, et al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it results in an enhanced

rate and degree of absorption of a pharmaceutically active agent, while minimizing gastric irritation, as explained by Wilson, et al.

* * * * *

Response to Arguments

Applicants' arguments filed on 7 February 2008 have been fully considered but they are not persuasive. (It should be noted that the submitted remarks were not paginated. Examiner refers to the first page of the remarks as page 1, etc.)

1. Applicants argue that the Wilson disclosure is limited to liquid and semi-solid dosage forms. *See* remarks, pages 1 and 2.

Examiner respectfully disagrees. At page 3, lines 20-22, Wilson states that the medicaments disclosed can be solidified to be used in hard capsules. Since applicants have not given a special definition to the term "solid", examiner will read the term in view of its broadest reasonable interpretation. As such, examiner respectfully submits that Wilson's solidified medicament reads on the instant claims.

2. Applicants argue that Wilson does not disclose an atorvastatin dosage form. *See* remarks, page 2.

It is noted that the feature upon which applicant relies (i.e., an atorvastatin dosage form) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims require a dosage form comprising atorvastatin, which is disclosed by the prior art (*see* rejection, above).

3. Applicants argue that the limitation "tablet" distinguishes the instant application from Wilson. *See* remarks, page 2.

In response to applicants' arguments, the recitation tablet has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

4. Applicants argue that the instant application is distinguished from Wilson by the limitation "direct compression." See remarks, page 2.

The process of direct compression disclosed in claim 1 is not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

5. Applicants argue that the Kerc reference is distinguished from the instant application because Kerc uses a granulation step. *See* remarks, page 3.

The direct compression without a granulation step disclosed in claim 1 is not essential to a determination of patentability of the composition disclosed in the claim. As mentioned above, the patentability of product-by-process claims is based on the product itself.

6. Applicants argue that Kerc discloses use of high concentrations of base while the instant application uses lower concentrations. *See* remarks, pages 3-4

One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Examiner respectfully submits that the Wilson reference was invoked in the Office action for a lower concentrations of base.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/
Primary Examiner, Art Unit 1618